

REMARKS/ARGUMENTS

Claims 15-24 are currently pending. Reconsideration of the rejections and passage to allowance are requested.

Rejections Under 35 U.S.C. § 112

The examiner has rejected claims 15-24 under 35 USC §112 first paragraph, alleging that the specification does not reasonably provide enablement for treating a proliferative disease in a mammal or human. The rejection is respectfully traversed.

It is well established that if *in vitro* tests correlate to a claimed method of invention, it constitutes a working example sufficient to provide enablement of the claims. See, e.g., MPEP 2164.02. This is particularly the case in instances where the state of the art recognizes such a correlation. In the present case, the compounds of the invention were shown to have activity in binding the BIR3 peptide binding pocket. Such activity has been shown to have a correlation to promoting apoptosis, which in turn has been shown to be a therapeutic method of treating proliferative disease. See, e.g., Kipp et al, "Molecular Targeting of Inhibitor of Apoptosis Proteins Based on Small Molecule Mimics of Natural Binding Partners," *Biochemistry*, Vol. 41(23), pp 7344-7349 (2002); and Arnt et al., "Synthetic Smac/DIABLO peptides enhance the effects of chemotherapeutic agents by binding XIAP and cIAP1 in Situ," *Journal of Biological Chemistry*, Vol. 277 (46), pp. 44236-44243 (2002); both cited in the present IDS. There is therefore a clear corollary recognized in the art between the activity demonstrated in the specification and the resulting potential as a therapeutic against proliferative disease.

The Examiner further states that, "proliferative disease encompass numerous and unrelated diseases, such as psoriasis and cancer. It is not understood how the administration of the compounds could embrace the treatment of such a large genus of diseases. It is for this that the rejection is maintained." See Office Action, page 3, first paragraph.

This is not the proper standard of enablement. A method of treatment is not being claimed. Where a composition of matter is claimed, the claimed subject matter does not have to provide enablement for a medicament to treat all of the diseases encompassed within proliferative diseases. It is only necessary to determine whether one of skill in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. See MPEP 2164.08. It is only necessary that the specification enables the claimed composition to treat a proliferative disease.

In the present case, the claims are directed to a composition of matter. There is no question as to whether the specification enables the claimed compound. Withdrawal and reconsideration of the rejection is required.

The examiner has also rejected claims 15-24 under 35 U.S.C §112 first paragraph, as failing to comply with the written description requirement. In particular the examiner states, "if a biomolecule is described only by a functional characteristic without any disclosed correlation between function and structure of the sequence, it is 'not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence'." (Page 12 of the Office Action).

The rejection is traversed as it is improper. Applicants clearly recite structural formula I in claim 15 and in the specification. The rejection is improper because the structure is definite and is described in the specification. The examiner even acknowledges that applicants have adequately described formulas I and II in the specification, but notes that there is insufficient description of "chemical modifications for membranes transport that would allow one of skill in the art to practice the invention as claimed." It is not required under 35 U.S.C. §112 however, to describe such chemical modifications beyond what is described in the present specification.

The purpose of the written description requirement is not that an applicant need to describe exactly the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. See, e.g., *In Re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). In the present case, it is acknowledged by applicants on page 7 of the application that, "substitutents that facilitate transport of the molecule across a cell membrane are known to those of skill in the medicinal chemistry art." The structure of the substitutents is further recited in the first full paragraph on page 7 as including, "a C₆-C₃₀ alkyl which is saturated, monosaturated, polyunsaturated, including methylene-interrupted polyene, phenyl, phenyl which [is] substituted by one or two C₁-C₈ alkyl groups, C₅-C₉ cycloalkyl, C₅-C₉ cycloalkyl which is substituted by one or two C₁-C₈ alkyl groups, X₁-C₅-C₉ cycloalkyl, or X₁-C₅-C₉ cycloalkyl, which is substituted by one or two C₁-C₈ alkyl groups; where X₁ is C₁-C₂₄ alkyl which is saturated, monosaturated, or polyunsaturated and straight or branched chain." The structural description in conjunction with the state of the art is therefore sufficient for written description requirements. Withdrawal of the rejection is respectfully requested.

The Examiner has also rejected claims 15-24 as amended in the previous response for introducing new matter into the application. The amendment of R8 as NR12R13 is supported by examples numbered 1, 12, 19, 20, 23, and 25 of the specification. The rejection is respectfully traversed.


Double Patenting Rejection

Applicants acknowledge the provisional rejection based upon of nonstatutory obviousness-type double patenting. Applicants also acknowledge that if all other rejections are traversed, this rejection should be withdrawn, as the present application has an earlier filing date than U.S. application No. 11/203,370, which is a continuation-in-part of the present application; see, e.g., MPEP 804. Accordingly, withdrawal of the rejection is respectfully requested.

The application is considered to be in condition for allowance and such action is solicited.

Respectfully submitted,

Novartis Institutes for BioMedical Research Inc.
Patent Department
400 Technology Square
Cambridge, MA 02139
(617) 871-7347
Date: December 20, 2007


Mark E. Baron
Attorney for Applicants
Reg. No. 46,150